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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,668	03/01/2002	Edward L. Blach	12460.4USC1	8126

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EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/087,668	<b>Applicant(s)</b> BLACH ET AL.	
	<b>Examiner</b> Glenn K. Dawson	<b>Art Unit</b> 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 and 43 is/are allowed.
- 6) ☐ Claim(s) 22, 25, 26, 28-40, 42, 44-47 is/are rejected.
- 7) ☐ Claim(s) 23, 24 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2-26-04, 1-19-06</u>  | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22,25,26 and 28-40,42 and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ierulli-6453901 in view of Muchin-5718224, Shippert-4274402 and either Heinecke-5088483 or Faasse-4744355.

Ierulli discloses the device as claimed including a nasal dilator having a release liner 60, a support layer 12 positioned between an engaging layer 14 and a surface layer 22. Also disclosed is the following manner of use:

In using the nasal dilator 10, the release liner 28 is removed and the dilator is applied over the nose 26 by aligning the separations 36 with the longitudinal line of the bridge of the nose, and then pressing the dilator against the skin along the opposite sides of the bridge.

It would appear from this discussion that the center portion of the dilator is applied before the end portions.

However, the release liner has only two portions instead of 3.

However, the examiner contends that providing three release liner portions instead of 2 is nothing more than a mere duplication of known parts.

#### B. Duplication of Parts

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies \*\* in the joint, and a plurality of "ribs" \*\* >projecting outwardly from each side of the web into one of the adjacent concrete slabs. <The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).

Muchin appears to teach the application of the central portion of the dilator to the nose first before the lateral side portions. The examiner gleans this from several aspects of the disclosure. In fig. 6, the dilator is shown being bent for application to the nose. The dotted line would appear to show the central portion being applied before the more spaced lateral portions. Additionally, given the inverted shape of the dilator before use, the examiner contends that adhering all of the portions simultaneously would be nearly impossible. If the end portions, or at least one end portion was/were applied before the central portion, then the user would be guessing at whether the center of the dilator were being placed at the proper centered location on the bridge of the nose of the user. If the ends were applied while merely viewing from above that the device was centered without actually touching the center portion of the adhesive to the bridge of the nose, when the center were actually pressed onto the bridge of the nose, there would almost certainly be air bubbles in the central region. Therefore, the examiner contends

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that given these disclosures, that even if it is not specifically recited, one skilled in the art would have recognized that the easiest manner of attachment of Muchin's dilator would have been to 1<sup>st</sup> adhere the central portion, (the portion closest the nose), and thereafter press the end portions into engagement with the tissue overlying the nasal passages.

Shippert actually discloses in col. 4 lines 20-36, that the central portion of an adhesively applied nasal splint is applied to the bridge of the nose before the lateral end portions are applied over the nasal passages.

Heinecke discloses an adhesive wound covering having as shown in fig. 2 a release liner of three components- a middle component 22, and two lateral components 24. In use, the middle component 22 is first removed from the covering, the adhesive which was protected by the central liner portion is pressed against the skin, the covering can then be properly positioned and then the lateral liner sections 24 can be peeled to expose lateral adhesive sections on the covering to be applied to spaced lateral locations around the wound.

Faasse discloses a wound covering having a release liner with actually two (2) central portions 30 and two lateral portions 20. Again, the central portions are removed thus exposing adhesive on the covering which is applied to the skin, the covering is properly positioned, and then the lateral liner portions are then removed exposing lateral adhesive portions on the covering which are applied to the neighboring skin.

It would have been obvious to have used a 3-piece liner in order to selectively uncover the central region of Ierulli's dilator because as Muchin indicates it was known

to position the central portion first. This would allow for easier handling of the device between the initial placement on the bridge of the nose without contacting the adhesive below the side regions. Note the teachings above of Heinecke and Faasse with regards to the use of the 3-component liner system to facilitate the placement of the covering on the body.

The result of being able to only remove the central liner portion to center the device on the nose prior to removing the liner portions on the adjacent portions in order to keep the adhesive on those lateral portions covered, clean and protected before the attachment of the lateral portions to the sides of the nose would not be unexpected. One skilled in the art would recognize that providing a release liner in 3 separate portions would afford the user the ability to adhere portions of the support to the skin of the user while allowing other portions of the adhesive to stay protected until needed to be exposed

Claims 22 and 31-33,42 and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muchin-'224 in view of Shippert and either Heinecke-5088483 or Faasse-4744355.

Muchin discloses the invention as claimed with the exception of the release liner being in 1 piece instead of 3.

Shippert actually discloses in col. 4 lines 20-36, that the central portion of an adhesively applied nasal splint is applied to the bridge of the nose before the lateral end portions are applied over the nasal passages.

Heinecke discloses an adhesive wound covering having as shown in fig. 2 a release liner of three components- a middle component 22, and two lateral components 24. In use, the middle component 22 is first removed from the covering, the adhesive which was protected by the central liner portion is pressed against the skin, the covering can then be properly positioned and then the lateral liner sections 24 can be peeled to expose lateral adhesive sections on the covering to be applied to spaced lateral locations around the wound.

Faasse discloses a wound covering having a release liner with actually two (2) central portions 30 and two lateral portions 20. Again, the central portions are removed thus exposing adhesive on the covering which is applied to the skin, the covering is properly positioned, and then the lateral liner portions are then removed exposing lateral adhesive portions on the covering which are applied to the neighboring skin.

It would have been obvious to have used a 3-piece liner in order to selectively uncover the central region of Muchin's dilator because as Muchin discloses it was known to position the central portion first. This would allow for easier handling of the device between the initial placement on the bridge of the nose without contacting the adhesive below the side regions. Note the teachings above of Heinecke and Faasse with regards to the use of the 3-component liner system to facilitate the placement of the covering on the body.

The result of being able to only remove the central liner portion to center the device on the nose prior to removing the liner portions on the adjacent portions in order to keep the adhesive on those lateral portions covered, clean and protected before the



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attachment of the lateral portions to the sides of the nose would not be unexpected.

One skilled in the art would recognize that providing a release liner in 3 separate portions would afford the user the ability to adhere portions of the support to the skin of the user while allowing other portions of the adhesive to stay protected until needed to be exposed.

***Terminal Disclaimer***

The terminal disclaimer filed on 02-02-2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6352548 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Arguments***

Applicant's arguments filed 02-02-2004 have been fully considered but they are not persuasive.

Applicant argues against the mere duplication of parts argument. The examiner contends that even if the prior art uses other structure to ensure centering of the device, that it would still be necessary to adhere the central portion 1<sup>st</sup> in order to take advantage of these centering means. It does no good to be able to see how the device should be centered on the nose, if it cannot be reliably placed there. One skilled in the art would have recognized the result as being expected. However, the examiner offered additional rationales for the modification of providing a 3<sup>rd</sup> liner not dependent on obvious duplication of known parts.

If the user were to hope of obtaining the centering of the dilator on the nose, then the examiner contends that the only way, or at the very least, the most obvious way, to ensure this is to first adhere the central portion. Otherwise, if the ends were applied simultaneously or prior to the center, either a bubble would be placed under the central portion, or the user would need to be merely guessing where to start to press the end portions on the nasal passage to get the center to be positioned exactly on the bridge of the nose of the user.

As the prior art shows usage of 3 liners to expose the center portion to get it properly positioned and then to remove the lateral liners to expose the end portions of the adhesive, the examiner contends that the claimed limitations are met.

The incorporation of the material from claim 23 into an apparatus claim will not make the claim allowable as it is merely intended use, which would not change the previously claimed structure at all.

***Allowable Subject Matter***

Claims 41 and 43 are allowed.


Claims 23,24 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Glenn K Dawson  
Primary Examiner  
Art Unit 3731

gkd  
11 August 2006